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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,781	01/02/2002	Christian Enggaard	P200000344 US	6319

23650 7590 07/15/2003

NOVO NORDISK OF NORTH AMERICA, INC
405 LEXINGTON AVENUE
SUITE 6400
NEW YORK, NY 10017

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/15/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,781

Applicant(s)

ENGGAARD, CHRISTIAN

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 14-25 is/are rejected.
- 7) ☒ Claim(s) 6 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-12 and 14-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Holman et al., 5,104,380.

As to claims 1, 19, 20, 23, 24 and 25, Holman et al. discloses a housing (8), a drive member (2), a spring means (6), a dose setting assembly (1, 3, 7, 12 and 26) in the housing connected to the spring means, the dose setting assembly comprising a dose setting member (3) moveable in a first direction against the bias of the spring means, and wherein the dose setting member is moveable in a second direction to adjust the set dose, see column 3, lines 12-22, a latch means (9) to retain the apparatus against the bias of the spring means, and the latch means being releasable to cause the drive member to expel the set dose from the syringe, see column 3, lines 28-32.

As to claim 2, the dose setting assembly further comprises a coupling member (25) in displaceable engagement with the dose setting member (3), see column 3, lines 14-15, the spring means acting on the coupling member, the coupling member acting on the dose setting member, see column 3, lines 12-22.

As to claims 3 and 12, the dose setting member and the coupling member comprise mutually cooperating surfaces such that movement of the dose setting member results in straining of the spring means, see column 3, lines 12-22.

As to claim 4, one (3 or 25) of the dose setting member and the coupling member is rotationally mounted on the drive member, the other (3 or 25) being arranged in sliding, non-rotational engagement with the drive member, see column 3, lines 12-40.

As to claim 5, the dose setting member (3, 4, 26) is rotationally mounted on a threaded portion of the drive member as claimed, see column 3, lines 35-40, and wherein the spring means acting on the coupling member in a direction corresponding to the longitudinal axis of the drive member, see column 3, lines 7-11.

As to claims 7 and 14, the coupling is between the cooperating surfaces (26) of the dose setting member and the coupling member (25) as claimed.

As to claims 8 and 9, the device further comprises a threaded member (4) with a first internal thread, see column 3, lines 37-38, the drive member (2) being a longitudinal drive member having an external thread corresponding to the first internal thread, as claimed, see column 3, lines 38-40.

As to claim 10, the dose setting member (3, 4 and 26) comprises a second internal thread, see column 3, lines 37-38, the dose setting member being rotationally mounted on the external thread of the piston drive member.

As to claim 11, the coupling member (25) is arranged in sliding, non-rotational engagement with the piston drive member, the spring means acting on the coupling member as claimed, see column 3, lines 7-20.

As to claims 15, 16, 17 and 22, the coupling is provided by coupling parts having surfaces provided with sector shaped teeth having ramp shaped edges, as claimed, see column 3, lines 12-20.

As to claim 18, the coupling is a one-way ratchet mechanism, see column 3, lines 16-20.

As to claim 21, a second latch means (32) is associated with the housing to retain the dose setting member in its coupled position, the second latch means being releasable to allow the dose setting member to disengage from the driving means.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 6 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements including a dose setting member moveable in a first direction to set a selected dose against the bias of the spring means, and moveable in a second direction to adjust the set dose, a coupling member, wherein the dose setting member and the coupling member allows the dose setting member to be rotated

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in either direction, yet preventing the spring means to counter rotate the dose setting member, was not found in the prior art search.

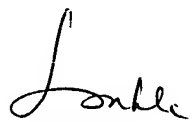
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.
July 14, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

07/14/03